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10/511,813	10/19/2004	Johannes Coy	4007.008	6538
30448	7590	12/13/2006		
AKERMAN SENTERFITT P.O. BOX 3188 WEST PALM BEACH, FL 33402-3188			EXAMINER AEDER, SEAN E	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/511,813	<b>Applicant(s)</b> COY, JOHANNES	
	<b>Examiner</b> Sean E. Aeder, Ph.D.	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 34-64 is/are pending in the application.
- 4a) Of the above claim(s) 39,41-43 and 51-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-38,40 and 44-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Detailed Action***

The Election filed 11/22/06 in response to the Office Action of 6/23/06 is acknowledged and has been entered. Applicant elected group I, a method for detecting the presence or absence of human transketolase like-1 polynucleotide expression, with traverse. Applicant also elected, with traverse, the following species: colon cancer and colon tumor; specific cell or specific tissue sample.

The traversal is on the ground(s) that Applicant disagrees with the Examiner that the technical feature linking group I-XVI is the human transketolase like-1 gene; rather, Applicant asserts that the special technical feature of the instant application is diagnosing cancer by the detection of human transketolase like-1 gene. Applicant particularly traverses with regard to the separation of groups I-IV, as Applicant indicates that the claims of groups I-IV are overtly related to the diagnosis of cancer by detection of human transketolase like-1 gene or polypeptide. Applicant states that the division of groups based upon polynucleotide or polypeptide expression is unnecessarily restrictive, because detection of the polypeptide serves to evidence presence and expression of the gene. Applicant further states that the kits claimed in groups II and IV utilize the same methods introduced in groups I and II. Applicant further argues that the species requirement for the various cancers should be withdrawn since colon, lung, and gastric cancer or tumor can be diagnosed according to the claimed method. Applicant further asserts that transketolase like-1 is produced regardless of the type of cancer or tumor being detected. Applicant further argues that the species requirement for the various samples should be withdrawn since Applicant asserts that the type of sample in

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no way affects the application of the special technical feature of testing for transketolase like-1 gene or protein. These arguments are not found persuasive.

In regards to the argument that the special technical feature of the instant application is diagnosing cancer by the detection of human transketolase like-1 gene, Examiner still maintains that the technical feature linking groups I-XVI is the human transketolase like-1 gene. However, diagnosing cancer by the detection of human transketolase like-1 gene does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the art. Mack and Markowitz (US 2003/0235820 A1; filed 2/27/02) teaches diagnosing cancer by the detection of human transketolase like-1 gene (see Table 17 and paragraphs 42-43, in particular).

In regards to separating the group I-IV, groups I and II are drawn to distinct methods and groups III and IV are drawn to distinct products. Each of the method groups represent materially distinct methods which differ at least in objectives, method steps, reagents, and criteria for success. Furthermore, each of the product groups represent distinct products. The DNA of group III is related to the protein of group IV by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. In the instant case, the search of the polypeptides and

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polynucleotides are not coextensive. The inventions of groups III and IV have a separate status in the art. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There are also distinct searches in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. A search of the nucleic acid molecules of group III would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group IV.

In regards to the statement that the kits claimed in groups II and IV utilize the same methods introduced in groups I and II, Examiner suspects Applicant intended to state that the kits claimed in groups III and IV can be used in the methods of group I or group II. Examiner would like to further point-out that the products of the kits of groups III and IV can be used in methods other than those claimed in groups I and II. Examiner would like to further point-out that when elected claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will eventually be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the

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rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope would an allowable product claim will not be rejoined. See MPEP § 821.04(b).

In regards to the argument that that the species requirement for the various cancers and corresponding tumors should be withdrawn, the various cancers and corresponding tumors do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the various cancers and their respective tumors represent separate and distinct cell types with different morphologies and functions such that one species could not be interchanged with the other. Further, the above species are distinct diseases which differ at least in etiology, pathology, and mechanisms. As such, each species requires different searches and the consideration of different patentability issues. Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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In regards to the argument that species requirement for the various samples should be withdrawn, the various samples do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent separate and distinct products which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 34-64 were pending.

Claims 39, 41-43, and 51-64 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claims 34-38, 40, and 44-50 are currently under consideration.

### ***Specification***

The specification is objected to because it contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. The specification discloses sequences by SEQ ID NO; however, the application lacks a sequence listing accompanied by a computer readable form (CFR). It is noted that an amendment addressing this objection must include the statement "the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing" and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).

### ***Claim Objections***

Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 49 recites: "The method according to claim 40, which is used for in-situ hybridization". It is noted that claim 49 is merely drawn to an intended use. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)).

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Claim 50 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 50 recites: "The method according to claim 34 which is used in the course of an in vivo or in vitro molecular imaging method". It is noted that claim 50 is merely drawn to an intended use. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-38, 40, and 44-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34, 40, and 44 and dependent claims 35-38, and 45-50 are rejected because claims 34, 40 and 44 recite the term "human transketolase like-1". The use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. Amending the claims to specifically and uniquely identify human transketolase like-1 by a SEQ ID NO can obviate the rejection.

Claim 34 and dependent claims 35-38, 40, and 44-50 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. Claim 34 recites a method for detection of disorders characterized by abnormal cell proliferation comprising detecting the presence or absence and/or level of expression of human transketolase like-1 gene in a biological sample and assessing diagnosis from said presence or absence and/or level of expression wherein presence of overexpression is indicative of disorders characterized by abnormal cell proliferation; however, the claim does not distinctly point out *to what* expression is compared in order to determine whether a level of expression is “overexpression”. Further, other than for “overexpression”, claim 34 does not make any kind of correlation of any other type of “abnormal expression” with the detection of a disorder. Thus, there are missing steps involving comparing and correlating. See MPEP § 2172.01.

Claim 48 recites: “The method according to claim 44, wherein the amplification reaction is PCR, LCR or NASBA”. There is insufficient antecedent basis the term “the amplification reaction” in the claim. It is suspected Applicant intended claim 48 to recite: “The method according to claim ~~44~~47, wherein the amplification reaction is PCR, LCR or NASBA”.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34-38, 40, and 44-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Mack and Markowitz (US 2003/0235820 A1; filed 2/27/02).

Claims 34-38 and 40 are drawn to a method for detecting colon cancer comprising detecting the presence or absence and/or the level of expression of human transketolase like-1 polynucleotide in a cell or tissue sample from an individual and assessing diagnosis, wherein the presence of overexpression is indicative of colon cancer. Claim 44 is drawn to a method of detecting the expression of human transketolase like-1 polynucleotide using a nucleic acid probe that hybridizes to a human transketolase like-1 polynucleotide. Claim 45 is drawn to the method of claim 44 wherein the probe is detectably labeled. Claim 46 is drawn to the method according to claim 45, wherein the label is selected from the group consisting of a radioisotope, a bioluminescent compound, a chemiluminescent compound, a fluorescent compound, a metal chelate, or an enzyme. Claim 47 is drawn to a method of detecting the expression of human transketolase like-1 polynucleotide using a nucleic acid amplification reaction. Claim 48 is drawn to the method of claim 44, wherein the amplification reaction is PCR, LCR or NASBA. Claim 49 is drawn to the method according to claim 40, which is used for in-situ hybridization. Claim 50 is drawn to the

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method according to claim 34 which is used in the course of an in vivo or in vitro molecular imaging method.

Mack and Markowitz teaches a method for detecting colon cancer comprising detecting the presence or absence and/or the level of expression of human transketolase like-1 polynucleotide in a cell or tissue sample from an individual and assessing diagnosis, wherein the presence of overexpression is indicative of colon cancer (see Table 17 and paragraphs 42-43, in particular). Mack and Markowitz further teaches a method of detecting the expression of human transketolase like-1 polynucleotide using a detectably labeled nucleic acid probe that hybridizes to a human transketolase like-1 polynucleotide (see paragraph 199, in particular), wherein the label is a radioisotope, a bioluminescent compound, a chemiluminescent compound, a fluorescent compound, or an enzyme (see paragraph 67, in particular). Mack and Markowitz further teaches a method of detecting the expression of human transketolase like-1 polynucleotide using a nucleic acid amplification reaction, wherein the amplification reaction is PCR or LCR (see paragraphs 143 and 198, in particular). Mack and Markowitz further teaches said hybridization methods can be performed in situ (see paragraph 205, in particular). One of skill in the art would recognize that the teachings of Mack and Markowitz described above encompass molecular imaging methods.

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### **Summary**

No claim is allowed.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SHANON A. FOLEY  
SUPERVISORY PATENT EXAMINER